

U.S.S.N. 10/669,869

Filed: September 23, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Claims

1. (currently amended) A dosage formulation for oral administration comprising an effective amount to treat a patient in need thereof of arsenic trioxide in the form of tablets, capsules, dispersions, or suspensions for oral administration when administered orally, wherein the amount is less than the effective amount for intravenous administration.
2. (previously presented) The dosage formulation of claim 1, wherein the arsenic trioxide is a powder.
3. (previously presented) The dosage formulation of claim 2, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.
4. (cancelled)
5. (previously presented) The dosage formulation of claim 1, further comprising at least one additional pharmacological agent.
6. (previously presented) The dosage formulation of claim 5, wherein the additional pharmacological agent is a chemotherapeutic.
7. (cancelled)
8. (cancelled)
9. (currently amended) The dosage formulation of claim [[4]] 1, wherein the final solution formulation has an arsenic trioxide concentration of 1 mg/ml.

Claims 10-27. (cancelled)

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28. (currently amended) A method of treating hematological malignancies in a subject in need thereof, the method comprising orally administering to the subject a therapeutically effective amount of an arsenic trioxide composition to produce a lower peak plasma concentration with fewer side effects less cardiotoxicity in the form of cardiac arrhythmias than the same amount of arsenic trioxide administered intravenously.

29. (previously presented) The method of claim 28, wherein the arsenic trioxide is a powder.

30. (original) The method of claim 29, wherein the arsenic trioxide powder has at least 90%, 95%, 96%, 97%, 98% or 99% purity.

31. (previously presented) The method of claim 28, wherein the arsenic trioxide is incompletely dissolved or dispersed in a solution.

32. (previously presented) The method of claim 28, wherein the arsenic trioxide is administered in a dosage of 5 to 10 mg/day.

33. (previously presented) The method of claim 28, wherein the arsenic trioxide is in a solution having a pH of 8.0.

34. (previously presented) The method of claim 28, wherein the arsenic trioxide is in a solution having a pH of 7.2.

Claims 35-37. (canceled)

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38. (previously presented) The method of claim 28, wherein the arsenic trioxide composition is orally administered to the subject daily at intervals for periods of weeks, a month or longer.

39. (previously presented) The method of claim 28, wherein the therapeutically effective amount is 10 mg per day.

40. (original) The method of claim 28, wherein the hematological malignancies is selected from the group consisting of acute myeloid leukemia, acute nonlymphocytic leukemia, myeloblastic leukemia, promyelocytic leukemia, myelomonocytic leukemia, monocytic leukemia, erythroleukemia, myelodysplastic syndrome, acute promyelocytic leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia, hairy cell leukemia, polycythemia vera, Hodgkin's lymphoma, non-Hodgkin's lymphomas, myeloma, giant cell myeloma, indolent myeloma, localized myeloma, multiple myeloma, plasma cell myeloma, sclerosing myeloma, solitary myeloma, smoldering multiple myeloma, nonsecretory myeloma, osteosclerotic myeloma, plasma cell leukemia, solitary plasmacytoma, and extramedullary plasmacytoma.

41. (original) The method of claim 28, wherein the hematological malignancies is acute myeloid leukemia.

42. (original) The method of claim 28, wherein the hematological malignancies is acute promyelocytic leukemia.

43. (previously presented) The method of claim 28 further comprising administering one or more additional chemotherapeutic agents.

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44. (previously presented) The dosage formulation of claim 1 in combination with one or more additional chemotherapeutic agents.

45. (new) The method of claim 28 wherein the arsenic trioxide composition is a tablet, capsule, dispersion or suspension.